



## MONOGRAPH

# Nirmatrelvir with ritonavir (Paxlovid®) Monograph - Paediatric

<b>Scope (Staff):</b>	Medical, Pharmacy, Nursing
<b>Scope (Area):</b>	All Clinical Areas

### Child Safe Organisation Statement of Commitment

CAHS commits to being a child safe organisation by applying the National Principles for Child Safe Organisations. This is a commitment to a strong culture supported by robust policies and procedures to reduce the likelihood of harm to children and young people.

This document should be read in conjunction with this [DISCLAIMER](#)

### QUICKLINKS

<a href="#">Dosage/Dosage Adjustments</a>	<a href="#">Administration</a>	<a href="#">Compatibility</a>	<a href="#">Monitoring</a>
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### DRUG CLASS

Antiviral with activity against severe acute respiratory syndrome coronavirus (SARS-CoV-2) also known as COVID-19.<sup>(1)</sup>

### INDICATIONS AND RESTRICTIONS

- Nirmatrelvir with ritonavir (Paxlovid®) may be considered in exceptional circumstances for the treatment of COVID-19 in children and adolescents  $\geq 12$  years and  $\geq 40$  kg who:
  - are within 5 days of symptom onset
  - do not require oxygen
  - are at high risk of deterioration
  - are not up to date with vaccination OR are immunosuppressed (regardless of immunisation status)<sup>(2)</sup>

Further information regarding high risk patients can be found in the [Australian guidelines for the clinical care of people with COVID-19](#).<sup>(2)</sup>

### Oral: Restricted (red) antiviral

ChAMP approval is required prior to prescription.

**CONTRAINDICATIONS**

- Hypersensitivity to nirmatrelvir, ritonavir or any component of the formulation.<sup>(3)</sup>
- Nirmatrelvir with ritonavir (Paxlovid®) is contraindicated in patients with severe renal impairment, severe hepatic impairment and in combination with other medications that are dependent on CYP3A4 for clearance where elevated concentrations are associated with harm.<sup>(3-5)</sup> Further information regarding potential interactions for nirmatrelvir with ritonavir (Paxlovid®) can be found on the [Liverpool COVID-19 interaction checker](#).

**PRECAUTIONS**

- For patients with renal impairment who require dose reduction, the additional tablets of nirmatrelvir should be removed prior to providing to the patient.<sup>(1, 4)</sup>
- Sexually active adolescent females should use effective contraception whilst taking nirmatrelvir with ritonavir (Paxlovid®).<sup>(3)</sup>

**FORMULATIONS**

Listed below are products available at PCH, other formulations may be available, check with pharmacy if required:

- Nirmatrelvir 150 mg tablets with ritonavir 100 mg tablets – co-packaged

**Imprest location:** Not on imprest, contact Pharmacy for individual patient stock

**DOSAGE & DOSAGE ADJUSTMENTS****Children <12 years of age and/or <40 kg:**

- Not recommended for this age group. Contact Infectious Diseases to discuss alternative options.

**Children and adolescents ≥12 years and ≥40 kg:**

- 300 mg nirmatrelvir (two 150 mg tablets) with 100 mg ritonavir (one 100 mg tablet) twice daily for a total of five days.<sup>(1)</sup>

**Renal impairment:**

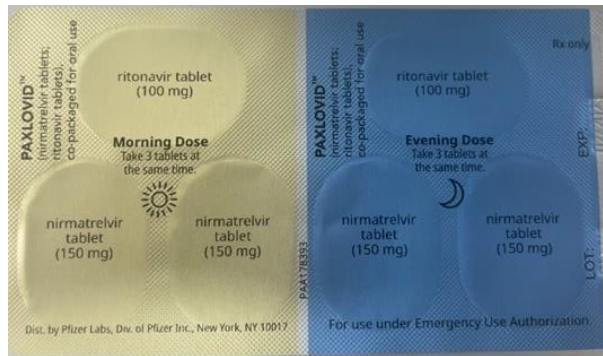
- [eGFR calculator](#)
- No dosage adjustment is required in patients with an eGFR of 60 mL/minute or greater.<sup>(4)</sup>
- eGFR 30 to 59 mL/minute: 150 mg nirmatrelvir (one 150mg tablet) with 100 mg ritonavir (one 100 mg tablet) twice daily for a total of five days.<sup>(1, 4)</sup>
- eGFR < 30 mL/minute: Contact Infectious Diseases to discuss alternative options.<sup>(1)</sup>

**Hepatic impairment:**

- No dose adjustment is required for patients with a Child-Pugh score of A and B. There is no data on use in patients with severe hepatic impairment (Child-Pugh score C) and nirmatrelvir with ritonavir (Paxlovid®) should not be used in these patients.<sup>(1, 4)</sup>

**Prescribing recommendations for inpatient use:**

- Nirmatrelvir with ritonavir (Paxlovid®) is only available as separate, co-packaged tablets.



- The patient must be charted for both agents separately on the medication chart as per the guide below:
  - Nirmatrelvir and ritonavir must be taken at the same time to ensure adequate nirmatrelvir levels are achieved.<sup>(1, 3, 5)</sup>

YEAR 20		DATE & MONTH																
				15/11														
PRESCRIBER MUST ENTER ADMINISTRATION TIMES																		
Date	Medication (Print Generic Name)																	
15/11	Nirmatrelvir													Task if Slow Release				
Route	DOSE	Frequency & now enter times																
PO	300mg	BD for 5 days												0800				
Pharmacy/Additional Information																		
2 x 150mg tablets														2000				
Indication																		
COVID-19														Calculation of Dose eg mg/kg/day				
Prescriber Signature	Print Name	Contact/Pager																
<i>D. Doctor</i>	Dr Doctor													Day				
												1	2	3	4	5		
Date	Medication (Print Generic Name)																	
15/11	Ritonavir 100mg tablet													Task if Slow Release				
Route	DOSE	Frequency & now enter times																
PO	100mg	BD for 5 days												0800				
Pharmacy/Additional Information																		
														2000				
Indication																		
COVID-19														Calculation of Dose eg mg/kg/day				
Prescriber Signature	Print Name	Contact/Pager																
<i>D. Doctor</i>	Dr Doctor													Day				
												1	2	3	4	5		

**ADMINISTRATION**

- Nirmatrelvir and ritonavir must be taken at the same time to ensure adequate nirmatrelvir levels are achieved.<sup>(1, 3, 5)</sup>
- Nirmatrelvir and ritonavir tablets are co-packaged with 5 daily blister cards. Each daily blister card contains a morning dose (two 150 mg nirmatrelvir tablets and one 100 mg ritonavir tablet) and evening dose (two 150 mg nirmatrelvir tablets and one 100 mg ritonavir tablet).<sup>(4)</sup>
- Nirmatrelvir and ritonavir (Paxlovid®) may be taken with or without food and should not be

cut, crushed or chewed.<sup>(1, 3, 4)</sup>

- If a dose of nirmatrelvir with ritonavir is missed by  $\leq 8$  hours, the dose should be taken as soon as possible. If the dose is missed by  $> 8$  hours, the subsequent dose should be taken at the next scheduled time. There is no need to give an additional dose to replace the missed dose.<sup>(4, 5)</sup>

### COMPATIBILITY (LIST IS NOT EXHAUSTIVE)

Not applicable

### MONITORING

Consider monitoring liver function tests and serum creatinine during treatment.<sup>(1)</sup>

### ADVERSE EFFECTS

**Common:** diarrhoea, vomiting, alteration in taste, headache<sup>(1, 3, 5)</sup>

**Infrequent:** Hypertension, myalgia<sup>(1, 3)</sup>

**Rare:** Toxic epidermal necrolysis, Stevens-Johnson syndrome, hypersensitivity reactions, angioedema<sup>(1, 5)</sup>

### STORAGE

Store below 25°C<sup>(3)</sup>

### INTERACTIONS

This medication may interact with other medications; consult PCH approved references (e.g. [Clinical Pharmacology](#)), a clinical pharmacist or PCH Medicines Information Service on extension 63546 for more information.

*\*\*Please note: The information contained in this guideline is to assist with the preparation and administration of nirmatrelvir with ritonavir (Paxlovid®). Any variations to the doses recommended should be clarified with the prescriber prior to administration\*\**

### Related CAHS internal policies, procedures and guidelines

[Antimicrobial Stewardship Policy](#)

[ChAMP Empiric Guidelines and Monographs](#)

[KEMH Neonatal Medication Protocols](#)

### References

1. Clinical Pharmacology [Internet]. Elsevier BV. 2022 [cited 23/06/2022]. Available from: <https://www-clinicalkey-com.pklibresources.health.wa.gov.au/pharmacology/>
2. Paediatric and Adolescent Care Panel. National COVID-19 Clinical Evidence Taskforce Melbourne2022 [Available from: <https://covid19evidence.net.au/>].
3. MIMS Australia. MIMS online [full product information]. St Leonards, N.S.W: CMP Medica

- Australia.; 2022. p. 1v. (various pagings).
4. McEvoy G, editor. AHFS Drug Information. Maryland: American Society of Health-System Pharmacists; 2022.
5. IBM Micromedex [Internet]. Truven Health Analytics. 2022 [cited 09/06/2022]. Available from: <http://www-micromedexsolutions-com.pklibresources.health.wa.gov.au/micromedex2/librarian>.


**Useful resources (including related forms)**

[National COVID-19 Clinical Evidence Taskforce – living guidelines](#)

[Patient Consent form](#)

[Patient medicines information leaflet](#)

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Healthy kids, healthy communities

Compassion

Excellence

Collaboration

Accountability

Equity

Respect

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